

REMARKS/ARUGMENTS

Upon entry of this reply, claims 1-20 will remain pending. Claims 1, 11, 13 and 20 are independent claims.

Reconsideration and allowance of the application are respectfully requested.

Response To Vacating Of Communication Mailed From Patent and Trademark Office On April 9, 2004

Applicants note that the Notice of Non-Responsive Amendment, mailed April 9, 2004 has been vacated, and that the present Final Office Action includes an action on the merits of claims 13 and 14, which are asserted to have been constructively elected, while holding claims 1-12 and 15-20 to be withdrawn from consideration as being directed to a non-elected invention. Applicants hereby express appreciation for the vacating of the Notice of Non-Responsive Amendment; however, for the reasons that will be set forth herein respectfully submit that an action on each of the pending claims is appropriate whereby withdrawal of the finality of the instant Office Action, and an action on the merits of each of the pending claims is respectfully requested.

Completion Of Record Regarding January 29, 2004 Interview

Applicants hereby confirm that a personal interview was conducted with the Examiner following his move to the new office location. The written file could not be located and the electronic file which is supposed to be present as an Image File Wrapper in the computer at the Patent and Trademark Office was not complete. Thus, the Examiner could not access the file, nor did he have a copy of the Amendment as filed. However, the Examiner did indicate that he was able to review his Office Action. The Examiner therefore indicated that the file was not available

on the Interview Summary form, and broadly indicated that amendments to the claims were discussed, and that the invention was discussed.

During the interview, Applicants utilized their file to discuss Applicants' invention with the Examiner in accordance with the amendments made in the response as previously filed and the prior art as discussed in the response. During the interview, the Examiner did not provide any opinions regarding the claims and their patentability over the prior art of record. It was therefore requested that the Examiner contact Applicants when reviewing the response if the Examiner deemed that any further information and/or amendment would be beneficial for advancing the application to issue. In the absence of any request for further information, and the mailing and vacating of the April 9, 2004 communication, and the issuance of the Final Office Action, Applicants are hereby ensuring that the record is complete by providing this discussion of the interview.

Response To Constructive Election And Request For Withdrawal Of Finality Of Office Action And Mailing Of A Complete Office Action On The Merits

The Office Action contends that claims 1-12 and 15-20 are directed to an invention that is independent or distinct from the invention originally claimed because the claims are drawn to cells capable of inducing cellular immunity, i.e., antigen presenting cells APCs (and methods of producing said cells) whereas the invention under examination is a method for inducing cellular immunity (and previously the effector cells of cellular immunity, CTL). Therefore, the Office Action asserts that since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, the Office Action indicates that claims 1-13 and 15-20 are withdrawn

from consideration as being directed to a non-elected invention citing 37 C.F.R. 1.142(b) and MPEP 821.30.

In response, Applicants respectfully submit that the claims as originally presented, especially in view of originally presented independent claim 13 and the disclosure in the specification should be considered to be directed to an originally claimed invention that has been clarified. Applicants respectfully submit that a reading of the originally filed specification and the originally filed claims, especially taken in context with originally filed claim 13, indicates that the a complete action on the merits required the consideration of Applicants' claims as presently pending. In particular, Applicants respectfully submit that the originally filed specification and claims readily reveal that Applicants' originally filed invention is directed to a cell capable of inducing cellular immunity, the cell being produced by reacting *in vitro* a complex comprising a hydrophobized polysaccharide and an antigen with an antigen-presenting cell.

Still further, Applicants note that this application is a national stage application, whereby unity of invention rules and procedures apply. In accordance with unity of invention, the presently pending claims have unity of invention, and are not properly divided. In order to establish that certain claims are constructively elected, and other claims are constructively non-elected, the Office Action must indicate how the claims are subject to restriction. In the instant situation, the requirement must establish how the claims lack unity of invention under the requirements of 37 C.F.R. 1.475. In this regard, Applicants respectfully submit that even if the claims are considered to be directed to a different invention than originally filed, which they are not, each of the pending claims is examinable together, because unity of invention is present with the claims under examination. In particular, a product and method can be claimed in the same application under the unity of invention rules.

In particular, it is noted that 37 C.F.R. 1.475 states:

§ 1.475 Unity of invention before the International Searching Authority, the International Preliminary Examining Authority and during the national stage.

(a) An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

(b) An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories:

(1) A product and a process specially adapted for the manufacture of said product; or
(2) A product and process of use of said product; or
(3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or

(4) A process and an apparatus or means specifically designed for carrying out the said process; or

(5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process.

(c) If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present.

(d) If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and § 1.476(c).

(e) The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

In the instant situation, the claims are directed to a product, a process specially adapted for the manufacture of the said product, and a use of the said product, whereby under 37 C.F.R.

1.475(b)(3) this national stage application containing claims to different categories of invention is considered to have unity of invention.

The Examiner is reminded that in accordance with Patent and Trademark Office procedure, when making a lack of unity of invention requirement, the examiner must (1) list the different

groups of claims and (2) explain why each group lacks unity with each other group (i.e., why there is no single general inventive concept) specifically describing the unique special technical feature in each group. In the present situation, the Office Action does not provide this listing of claims, and does not explain why each group lacks unity with each other group.

In view of the above, Applicants respectfully request a complete action on the merits of each of the pending claims because unity of invention is present. Moreover, Applicants respectfully request withdrawal of finality of the Office Action.

Information Disclosure Statements

Applicants note that a Second Supplemental Information Disclosure Statement has been filed on July 2, 2004. The Examiner is respectfully requested to indicate consideration of this disclosure statement by initialing the Form PTO-1449 submitted therewith with the next communication from the Patent and Trademark Office.

Response To Rejections Based Upon Prior Art

Claims 13-14 remain rejected under 35 U.S.C. 103(a) as obvious over Nestle et al. (hereinafter "Nestle"), Nature Medicine, Vol. 4, No. 3, pp. 328-332 (1998), in view of Jiang et al. (hereinafter "Jiang"), Nature, Vol. 375, 11 May 1995, pp. 151-155. The rejection asserts that Nestle teaches a method of inducing cellular immunity comprising isolating an APC, reacting said APC with a tumor antigen and returning the cell to the body. The rejection asserts that Jiang teaches that the dendritic cell homolog of the macrophage mannose receptor can facilitate a 100-fold increase in the uptake and presentation of antigen by a dendritic cell. The rejection concludes by asserting that it would have been obvious to one of skill in the art to combine Nestle and Jiang to obtain the claimed invention by, amongst other steps, isolating an APC, reacting the

APC with a tumor antigen, and returning the resulting cell to the living body by parenteral administration, as taught by Nestle, including a hydrophobized polysaccharide complex (such as mannan) in the reaction of the antigen with APC. The rejection attempts to support the addition of mannan complex to the reaction by asserting that the addition would have been expected to increase the uptake and presentation by the DC, given the teachings of Jiang that activation of the DC homolog of the macrophage mannose receptor (DEC-205) can facilitate a 100-fold increase in the uptake and presentation of the antigen by DC.

In response and as previously noted by Applicants, Applicants' rejected claims 13 and 14 include, amongst other features recited therein, a method for inducing cellular immunity *in vivo* comprising isolating an antigen-presenting cell from a living body and reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell. Applicants again respectfully submit that one having ordinary skill in the art would not have been motivated to combine the disclosures of Nestle and Jiang as asserted in the Office Action. However, even if for the sake of argument, the disclosures were combined, Applicants again respectfully submit that neither of Nestle nor Jiang discloses reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell. Therefore, no combination of Nestle and Jiang would include a hydrophobized polysaccharide-antigen complex.

For example, Nestle teaches that the *in vitro* creation of an antigen-dendritic cell yields an increase in the immune response of inoculated patients. Nestle reports the vaccination of 16 melanoma patients with peptides or tumor lysates using dendritic cells for antigen delivery, but does not teach or suggest reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell.

In an attempt to overcome the deficiencies of Nestle, the rejection utilizes Jiang. However, one having ordinary skill in the art would not have sought to modify the disclosure of Nestle based upon Jiang. There is no motivation to combine the disclosures of Jiang with that of Nestle. However, even if for the sake of argument the disclosures were combined, no combination of Nestle and Jiang would include a hydrophobized polysaccharide-antigen complex. Jiang teaches that antigen presenting functions of dendritic cells is associated with the high-level expression of a specific receptor, DEC-205. Jiang concludes that dendritic cells and thymic epithelial cells express a novel receptor, DEC-205, which contributes to antigen presentation. Thus, the combination of these two documents would, at most, lead to an antigen-dendritic cell overexpressing DEC-205, and not the currently claimed method including a hydrophobized polysaccharide-antigen-cell complex.

The present Office Action contends that, in view of the prior art, sound scientific reasoning renders the method of the instant claims obvious. It is asserted in the Office Action that Nestle teaches loading APC (that had to have been previously isolated from a living body) with tumor antigens for return to a patient (living body) for the induction of CTLs (cellular immunity). It is also asserted that Jiang teaches a way to facilitate the loading of APC, i.e., the use of a hydrophobized polysaccharide. From these assertions, the Office Action concludes that the combined references comprise an improved method and render the method of the instant claims obvious.

With respect to the contentions in the Office Action, Applicants note that the comments in the Office Action relate to the individual disclosures of Nestle and Jiang, and do not indicate how the disclosures are being combined. Moreover, the comments in the Office Action do not indicate how any combination of Nestle and Jiang would arrive at Applicants' claimed invention which

includes, as recited in independent claim 13, a method for inducing cellular immunity *in vivo* comprising isolating an antigen-presenting cell from a living body, reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell, and returning the resulting cell to the living body. Therefore, if the rejection is maintained, the Examiner is respectfully requested to clarify the rejection to establish where any proper combination of Nestle and Jiang would arrive at a method for inducing cellular immunity *in vivo* which comprises isolating an antigen-presenting cell from a living body, reacting a complex comprising a hydrophobized polysaccharide and an antigen with the antigen-presenting cell, and returning the resulting cell to the living body.

Applicants respectfully submit that a *prima facie* case of obviousness has not been established. However, even if for the sake of argument a *prima facie* case of obviousness is considered to be established, Applicants note that the hydrophobized polysaccharide according to the present invention can form a complex with a tumor antigen, whereas a polysaccharide in the prior art cannot form a complex with a tumor antigen. Thus, for this additional reason, the presently claimed invention would not have been obvious to one skilled in the art whether or not uptake of hydrophobized polysaccharide in cytoplasm is attributable to DEC-205, even though the DEC-205 is known to be responsible for the uptake of polysaccharide in cytoplasm.

For the reasons set forth above, Applicants' claimed invention is not taught or suggested by the prior art, whereby the claims are patentable over the prior art of record, and the rejections should be withdrawn.

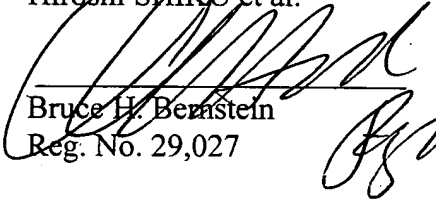
CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow each of the pending claims.

Applicants therefore respectfully request that an early indication of allowance of the application be indicated by the mailing of the Notices of Allowance and Allowability.

Should the Examiner have any questions regarding this application, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully submitted,
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